Complete Summary

GUIDELINE TITLE

Management of alloimmunization during pregnancy.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Management of alloimmunization during pregnancy. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2006 Aug. 8 p. (ACOG practice bulletin; no. 75). [31 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

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SCOPE

DISEASE/CONDITION(S)

Alloimmunization during pregnancy and associated fetal hemolytic disease (fetal erythroblastosis, fetal anemia)

GUIDELINE CATEGORY

Diagnosis Management

CLINICAL SPECIALTY

Allergy and Immunology Hematology Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review screening methods and management of alloimmunization in pregnant women

TARGET POPULATION

Pregnant women whose fetus may carry blood group factors inherited from the father that are not possessed by the mother

INTERVENTIONS AND PRACTICES CONSIDERED

Screening

- 1. Maternal blood type
- 2. Maternal serum antibody titers (except in Kell-sensitized mothers or mothers with a previously affected fetus)
- 3. Paternal erythrocyte antigen status
- 4. Amniocentesis for fetal antigen type
- 5. Spectral analysis of amniotic fluid bilirubin levels to predict fetal anemia
- 6. Middle cerebral artery Doppler ultrasonography to predict fetal anemia (preferred)

Management

- 1. Maternal anti-D immune globulin administration for Rh-negative women not previously sensitized to D
- 2. Fetal cordocentesis
- 3. Intrauterine transfusion
- 4. Preterm delivery (with maternal steroid administration, as appropriate, to enhance fetal pulmonary maturity)

MAJOR OUTCOMES CONSIDERED

Perinatal morbidity and mortality

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between November 1965 and June 2005. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- **I** Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1** Evidence obtained from well-designed controlled trials without randomization.
- **II-2** Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3** Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III** Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician—gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

- **Level A** Recommendations are based on good and consistent scientific evidence.
- **Level B** Recommendations are based on limited or inconsistent scientific evidence.
- **Level C** Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

The following recommendations are based on good and consistent scientific evidence (Level A):

- In a center with trained personnel and when the fetus is at an appropriate gestational age, Doppler measurement of peak systolic velocity in the fetal middle cerebral artery is an appropriate noninvasive means to monitor pregnancies complicated by red cell alloimmunization.
- The initial management of a pregnancy involving an alloimmunized patient is determination of the paternal erythrocyte antigen status.
- Serial titers are not useful for monitoring fetal status when the mother has had a previously affected fetus or neonate.
- Antibody titers are not appropriate for monitoring Kell-sensitized patients because Kell antibodies do not correlate with fetal status.
- Anti-D immune globulin is indicated only in Rh-negative women who are not previously sensitized to D.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial.

- **II-1** Evidence obtained from well-designed controlled trials without randomization.
- **II-2** Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3** Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III** Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendation

- **Level A** Recommendations are based on good and consistent scientific evidence.
- **Level B** Recommendations are based on limited or inconsistent scientific evidence.
- **Level C** Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of alloimmunization during pregnancy

POTENTIAL HARMS

Higher alloimmunization false-positive rate after 34 to 35 weeks of gestation with middle cerebral artery Doppler ultrasonographic

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators Foreign Language Translations Patient Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Aug

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Obstetrics

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Proposed performance measures are included in the original guideline document.

PATIENT RESOURCES

The following is available:

• The Rh factor. How it can affect your pregnancy. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2005.

Electronic copies: Available from the <u>American College of Obstetricians and Gynecologists (ACOG) Web site</u>. Copies are also available in Spanish.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

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NGC STATUS

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